United States Court of Appeals

for the Second Circuit

APPELLANT'S REPLY BRIEF

ORIGINAL WITH PROOF OF SERVICE

76-6169

To Be Argued By:
JOSEPH H. EINSTEIN

UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

B
P/S

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP.,
DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

and

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

On Appeal from a Judgment of the United States District Court for the Eastern District of New York

REPLY BRIEF OF APPELLANTS

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Preliminary Statement

The answering brief submitted by the government fails to respond to the critical issues raised on this appeal. Here, as throughout this proceeding, the government relies on ad hominem scare tactics and ignores the important issues of law presented by this matter.

We shall here respond to some of the more major oversights found in the answering brief submitted by the government. Since many of the matters raised have already been adequately dealt with in appellants' main brief, we shall not repeat what is set forth therein. Our silence on any particular point should not be deemed acquiescence.

THE GOVERNMENT'S BRIEF CONTAINS NUMEROUS MISSTATEMENTS OF FACT

A review of the brief submitted by the government demonstrates that there are numerous inaccurate factual statements contained therein. We shall here mention but a few of them.

A

The government suggests (Brief pp. 3, 30) that a lethal toxin may develop in situations where the brining and cooking of smoked fish are inadequate. This is not accurate. If smoked fish is treated as a perishible product - which it is - and is properly refrigerated, there will be no outgrowth of the botulinum spores and no development of toxin, regardless of brining and cook-

ing levels. It is only when the product is abused by not being refrigerated that any spores which may be present may grow and create a toxin. However, smoked fish is marketed as a refrigerated, perishible product (332-336, 572-574, 578).

B

The government has erroneously described the extent of Nova Scotia's smoked whitefish business (Brief, p. 4, fn. 5). In fact, this product alone accounts for ten (10%) percent of Nova Scotia's business; not four (4%) percent as suggested by the government. The deleterious effect of the injunction on defendants' business was clearly demonstrated at trial (340-342, 355-359, 379-381).

C

Notwithstanding the protestations to the contrary (Brief, pp. 5, 30), the trial evidence clearly demonstrated that whitefish produced in accordance with the GMP were

not marketable. Six processors and three independent witnesses so testified (See Appellants' Brief, pp. 7-8). The court below concluded "that a product made under the parameters would not be marketable in the greater New York area nor probably in Florida." (722). The government introduced no evidence tending to show that whitefish produced in accord with the GMP would be marketable anywhere.

D

At page 6, the government asserts that a reasonable possibility of injury to health exists if the time-temperature-salinity requirements of the GMP are not adhered to. We respectfully submit that the absence of a single case of botulism illness since 1963 clearly demonstrates otherwise - especially in view of the fact that the processing parameters of the GMP have never been followed.

E

The government, in its description of the "administrative" record (Brief pp. 18-19), fails to note that the

"record" entirely omits any reference to the critical meeting with Gen. Fred Delmore of FDA at which industry vigorously voiced its objections to the proposed GMP and to FDA's broken promise to consult further with industry and issue new proposed regulations for further comment by industry (225-231, 236-237, 412-416, 617-619). This omission is all the more striking in view of the government's assertion that FDA in fact responded to and considered industry comments with respect to the proposed regulation (Brief pp. 20, 22, 36).

F

Similarly, the government's reference to FDA's own marketability study (Brief p. 19) again shows the cavalier attitude of FDA. Rather than give serious consideration to industry views as to marketability and safety, FDA chose to proceed upon the basis of its own private, intra-agency test. This test was a biased and inconclusive opinionated evaluation by a non-representative group of consumers.

F

The government's suggestion (Brief pp. 30-31) and the district court's conclusion that processing methods exist which will admit of compliance with the GMP are erroneous. There is not one shred of evidence to demonstrate the existence of such methods (see Appellants' Brief pp. 7-8).

G

At page 24 of its brief, the government seeks to support the regulation on the ground that the undisclosed scientific data "was considered by FDA at the time it promulgated the regulations." This statement is erroneous. The record is barren of any evidence as to what material was actually considered. No effort was made to obtain this critical information when, in 1976, FDA first undertook to compile the "administrative record." (273-274).

POINT I

THE REGULATION EXCEEDS THE SCOPE OF THE STATUTE

The government, in its defense of the regulation

at issue here, has either deliberately or inadvertently misunderstood the basic thrust of Nova Scotia's challenge to the validity of the portion of the GMP regulation at issue here.

Throughout Point I of its brief, the government has attempted to argue that Section 402(a)(4) of the Act, 21 U.S.C. §342(a)(4), is not limited to conventional varieties of "filth" (e.g., Brief pp. 7-8, 12, 16). At best this argument is peripheral to the main issue here. The crucial issue here is whether the phrase "prepared, packed or held under insanitary conditions" includes the preparation of food under concededly clean conditions which has not been processed in a manner which FDA asserts is necessary to eliminate naturally occurring bacteria. We submit that the statutory language simply does not support the regulation.

The reliance by the government and the district court upon United States v. Sprague, 208 Fed. 419 (E.D.N.Y. 1913), evidences this basic misunderstanding of appellants'

challenge to the regulation. In that case, which was decided over sixty years ago, the district court held that the presence of bacteria in oysters rendered them "filthy." The decision had absolutely nothing to do with whether the oysters were prepared, packed or held under insanitary conditions. The holding of the case, like much of the government's brief, is thus irrelevant to the issue before this Court.*

In addition to having virtually ignored the main thrust of appellants' argument, the government, relying upon the district court's opinion, has attempted to ignore the language of the statute under which the regulation was promulgated. Section 342(a)(4) defines adulterated food to include food which

> has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. (Emphasis Added).

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* There is no showing that any of defendants' whitefish contained botulinum spores (137, 531-532).

Clearly, this portion of the statute does not cover all food which may have become contaminated or injurious to health, but only food which has become so due to being prepared, packed or held under insanitary conditions. The description of the manufacturing conditions as "insanitary" is not "secondary" as FDA and the district court asserted. (Brief pp. 10-11; A-733). Rather, it is a primary element of the statute which limits the applicability of the two "whereby" clauses to only those foods prepared, packed or held under insanitary conditions.

We are not here concerned with whether the regulation can be supported under any other statutory provision* because the sole statutory authority for the regulation is 21 U.S.C. §342(a)(4).

The government asserts that "it is not the nature of the contaminant, but its potential effect that determines whether the failure adequately to heat and brine smoked whitefish constitutes an insanitary condition."

---

* We submit that no other provision of Section 342(a) will support the regulation.

(Brief p. 11). This argument ignores the plain meaning of the statute under which the regulation was promulgated. Under 21 U.S.C. §342(a)(4), it is the source of the alleged contaminant which is the prerequisite to the applicability of the statutory provision.* Only after it has been determined that insanitary conditions exist in the preparing, packing or holding of food does the inquiry progress to determine whether the food has become contaminated with filth or rendered injurious to health.

The government's reliance upon National Confectioners Assn. v. Mathews, CCH Feed, Drug & Cosmetic Law Rep. §38,062 (D.D.C. 1976), is misplaced. That case is totally irrelevant to the issue in this case. The plaintiff in National Confectioners sought to bar the enforcement of regulations requiring coding and record keeping of processed food products which were designed "to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for human consumption." 21 C.F.R. §128c.8(c) (Emphasis Added). The court's ruling that such regulations were authorized by

* The district court recognized that the "bacterial infestation here is not one that invades the fish during processing" (736). That simple recognition demolishes the government's case.

the statute indicates only that the FDA has the authority under Section 342(a)(4) to promulgate regulations concerning the identification and recall of foods processed under insanitary conditions. That power is not in issue in this litigation. National Confectioners does not support the power of the FDA to promulgate the type of processing regulations which are at issue here.

Neither the government nor the district court cited any authority for the proposition that the phrase "prepared, packed or held under insanitary conditions" embraces food that has been prepared, packed or held under sanitary conditions. Yet this is the result reached below.

The district court, in its opinion, incorrectly concluded that the time-temperature-salinity requirements were within the statutory authority granted to FDA. The court recognized that the statute "literally seems(s) to deal only with conditions brought about by processing itself" (734). However, the court then commented that "seen in

the perspective of Part 128a's purpose and the purpose in subsection (a)(4), the use of the word "insanitary" ... is not inadequate" to include the processing requirements of the GMP. But this reasoning is wide of the mark. In essence, the court concluded that Section 342(a)(4) grants FDA the authority to promulgate time-temperature-salinity requirements simply because FDA has interpreted the statute in this fashion.* This approach to the statute and regulation violates the basic principle of administrative law that administrative agencies may not make law, but are limited to promulgating regulations that are authorized by statute. The regulation at issue here is valid only

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* In defining the term "insanitary conditions", FDA has taken an approach similar to that taken by Humpty Dumpty in Lewis Carroll's Through the Looking Glass" (Ch. VI): "When I used a word, Humpty Dumpty said, in a rather scornful tone, "it means just what I choose it to mean - neither more nor less."

"The question is, "said Alice, "whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "which is to be master - that's all."

if Section 342(a)(4) grants FDA the power to promulgate it. As discussed in Point I of our main brief, the statute did not give FDA such power. Consequently, the regulation is invalid.

In a desperate effort to support its position, the government refers to other regulations promulgated under Section 342(a)(4) (Brief p. 15). We submit that excessive and illegal regulation cannot be rationalized by pointing to other equally excessive and illegal regulation.

The government also suggests (Brief p. 15), that in construing the term "insanitary conditions", this Court should recognize that the problem is a practical one of consumer protection, not dialectics. Defendants and the entire smoked fish industry are concerned with consumer protection. This concern is evidenced by the abandonment of vacuum packaging of whitefish and by their admitted compliance with all sanitary requirements of the GMP. Moreover, given the absence of a single reported case of botulism illness in hot smoked fish since 1963, it certainly

appears that the government is engaged in a flight of fancy.

Be that as it may, FDA cannot, simply by waving the banner of consumer protection, support its promulgation of a regulation far in excess of its statutory authority. The issue here is not one of "dialectics", but one of substance concerning the Court's obligation to control and limit administrative power run wild. In Section 342(a)(4), Congress gave FDA the power to regulate food which may have become contaminated or may have been rendered injurious to health, but that power was specifically limited by Congress to instances occurring as the result of insanitary conditions in preparing, packing and holding of food. The fact that FDA has promulgated a regulation in excess of this statutory authority cannot be excused because of FDA's alleged good intentions.

The regulation exceeds the authority granted to FDA under the statute and is invalid.

POINT II

THE REGULATION WAS IMPROPERTY PROMULGATED

A

In our main brief (Point II), we demonstrated that FDA improperly promulgated the regulation at bar becase, inter alia,it improperly failed to disclose its reliance upon scientific data which was then proffered at trial as supportive of the regulation.

The government has not responded to our suggestion that disclosure of this reliance would have afforded those being regulated an opportunity to rebut the scientifically invalid premises contained in that data. Rather, the government suggests (Brief pp. 20-21) that the data was not secret and its existence could have been ascertained by those concerned. But this claim is erroneous because the trial evidence demonstrated that the "scientific evidence" was not actually available to those being regulated.

The situation is akin to that in Portland Cement

Ass'n v. Ruckelshaus, 486 F.2d 373 (D.C. Cir. 1973), cert denied, 417 U.S. 921 (1974), where the Court held (at 393):

> We find a critical defect in the decision-making process in arriving at the standard under review in the initial inability of petitioners to obtain - in timely fashion - the test results and procedures used on existing plants which formed a partial basis for the emission control level adopted...."

The record here contains extensive surveys and tests which the government now asserts support FDA's action. However, it is clear that the reliance by FDA on this material was not disclosed. Moreover, as Portland Cement, supra, demonstrates, the specific data, not a hugh bulk of material, must be referred to and disclosed. As the Court noted (at 400):

> In this connection, a comment on the proper use of scientific literature may be in order. If such literature is relied upon, the agency should indicate which particular findings of that literature are significant. A generalized reference, to a work as a whole, will avail the agency little if a problem arises on judicial review. On remand, any findings in the literature that are relied on by EPA should be specifically indicated.

Thus, the government's argument that the regulation should be sustained because the material contained in the

purported record was either known or accessible is untenable.

B

The government suggests that even if it acted improperly in promulgating the regulation at bar, its improper behavior should nonetheless be excused because the applicable standards were more lax in 1970 when the regulation was promulgated than they are now (See e.g., Brief pp. 22, 37-38).

This argument is specious.

Many of the decisions on which appellants rely were on the books in 1970. So was the Administrative Procedure Act. It would be a gross injustice to appellants for them to be driven out of business by an invalid regulation. Appellants stand in jeopardy today. Their rights should be judged by today's standards.*

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* The suggestion that laches is applicable is absurd. The government waited six years to bring this action. Throughout that time, Nova Scotia voiced its vehement disagreement with the regulation and admittedly did not complay (285-290, PX-3, PX-4).

Certainly laches would apply no more to defendants' failure to challenge the regulation over the past years than it would to the government's failure to seek enforcement during the same period.

As is noted by Professor Moore, 1B Moore's Fed Prac. §0.402[3.-2-1] at 171:

> The general rule is and has been for centuries past that judicial precedents normally have retroactive as well as prospective effect. That is, what a court holds to be the law today, for the litigants before it, is the law

*(footnote continued) Moreover, we know of no instance where laches has been applied to bar a litigant from defendant himself. Laches bars suits, not defenses.

It is interesting to note that in Abbott Labs v. Gardner, 387 U.S. 155 (1967), the sole case cited by the government on this matter, the Court had occasion to consider the Congressional intent and general purpose of the judicial review provisions of the Administrative Procedure Act. In its discussion, the Court stated (at 140-141):

> The legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed that theme by noting that the Administrative Procedure Act's "generous review provisions" must be given a "hospitable" interpretation.

Indeed the government's position here is directly contrary to that taken at trial, where its attorney told the court below (140):

> Your Honor, we don't quarrel with their right to challenge the regulation now.

> for persons who subsequently come before the court, even though the cause of action or defense of such persons arose before today's decision. Today's decision may make actionable that which was not actionable; or recognize a defense that which before was not a valid defense.

C

The government also suggests that FDA's heavy handed action can be justified upon the principle of administrative expertise (Brief pp. 24-27). While we do not question that an administrative agency may rely upon expertise, we submit that where that expertise consists of scientific information - as it did here - such reliance and information must be disclosed, in advance, to those being regulated so that they are afforded an opportunity to meet and rebut the "expertise" of the agency. Expertise in this context, after all, is nothing more or less than a species of factual information possessed by a regulatory body. Persons who are about to be regulated based upon that factual knowledge are entitled to be advised of the basis of the regulation.

This principle is illustrated by the decision in Abbotts Daries Division of Fairmont Foods, Inc. v. Butz,

389 F.Supp. 1 (E.D. Pa. 1975), where the Court noted (at 9-11):

> There is, however, no precedent which allows the Secretary to make a decision based solely on his administrative expertise and knowledge unless it has been introduced as evidence in a hearing record.
>
> * * *
>
> While administrative expertise does encompass powers of analysis not possessed by others, such analysis must be justified by reference to objective evidence, Fairmont Foods Co. v. Hardin, supra, 442 F.2d at 772. I agree with the District of Columbia Court of Appeals when it says that administrative expertise is strengthened, not crippled by a requirement of substantial evidence, Greater Boston Television Corp. v. FCC, 143 U.S. App. D.C. 383, 444 F.2d 841, 850 (1971), cert. denied, 406 U.S. 950, 92 S.Ct. 2042, 32 L.Ed.2d 338 (1972).
>
> The Supreme Court has warned:
>
> Expert discretion is the lifeblood of the administrative process, but "unless we make the requirements for administrative action strict and demanding, expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion." [It's] for the courts to determine whether the agency has [abused its discretion.] (citations omitted)

Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167-168, 83 S.Ct. 239, 245, 9 L.Ed.2d 207 (1962). See Baltimore & Ohio R. Co. v. Aberdeen R. R. Co., 393 U.S. 87, 91-92, 89 S.Ct. 280, 283, 21 L.Ed.2d 219 (1968), rehearing denied, 393 U.S. 1124, 89 S.Ct. 987, 22 L.Ed.2d 131 (1969).

The Secretary's second assumption, that evidence to support his finding need not be placed into the record has been touched on in the above discussion. The requirement that administrative findings be supported by substantial evidence requires the government to introduce evidence if its findings will not be supported by the record created by non-government witnesses. Reliance exclusively on agency expertise is insufficient. Administrative expertise is the value of the administrator's experience in interpreting and analyzing facts to make the proper findings and decision. However, to make findings without facts is like building a house without a foundation.

The purpose of requiring the government to produce evidence at a hearing is twofold. First, it will create an evidentiary record on which the Secretary can make his findings based on clear and rational choices. It allows a court to understand the basis for the Secretary's decision and intelligently rule on whether the decision is lawful and supported by substantial evidence.

Secondly, to require the introduction of evidence by the government and force it to reveal publicly the facts which

> form the basis for the Secretary's deci sion allows interested parties to test, refute, rebut or buttress these facts. This is what a fact finding hearing is all about. It is an educational process, not only for the Secretary, but also for the public, Congress and the courts so that ultimately the best decision is made. For the Secretary to hide the facts behind a facade of administrative expertise would be to frustrate the congressional intent of the Agricultural Adjustment Act and the Administrative Procedure Act. The facts could then never be challenged, never tested. Ultimately the absence of facts would result in incestuously perverting administrative integrity and public confidence in government.

In International Brotherhood of Elec. Workers v. NLRB, 487 F.2d 1143 (D.C. Cir. 1973), aff'd, sub nom, Florida Power & Light Co. v. International Brotherhood of Elec. Workers, 417 U.S. 790 (1974), cert denied, sub nom, Bell Supervisors Protective Assn. v. NLRB, 418 U.S. 904 (1974), the Court had occasion to comment upon the role of administrative "expertise"in regulatory proceedings (at 1170-1171):

> To be sure, the Labor Board is entitled to great deference when it interprets the act it administers. See, e.g., Brooks v. NLRB, 348 U.S. 96, 75 S.Ct. 176, 99 L.Ed. 125 (1954); Republic Aviation Corp. v. NLRB, 324 U.S. 793,

> 65 S.Ct. 982, 89 L.Ed. 1372 (1945). But this deference has its limits. In the final analysis, "administrative experience is of weight in judicial review only to this point - it is a persuasive reason for deference to the [Board] in the exercise of its discretionary powers under and within the law. It cannot be invoked to support action outside of the law. And what action is, and what is not, within the law must be determined by courts, when authorized to review, no matter how much deference is due to the agency's fact finding. Surely an administrative agency is not a law unto itself * * *." SEC. v. Chenery Corp., 332 U.S. 194, 215, 67 S.Ct. 1960, 1762, 91 L.Ed. 1995 (1947) (Mr. Justice Jackson, dissenting).

In the case at bar, "agency expertise" simply will not excuse the gross impropriety practiced by FDA in promulgating the regulation at bar.

CONCLUSION

The judgment below should be reversed or appropriately modified.

Respectfully submitted,

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STATE OF NEW YORK)
COUNTY OF NEW YORK) ss.:

JEFF ELYSHEVITZ, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age and resides at 90-19 88th Ave. Woodhaven, NY 11421

That on the 18 day of FEBRUARY, 1977, deponent personally served the within REPLY BRIEF OF APPELLANTS upon the attorneys designated below who represent the indicated parties in this action and at the addresses below stated which are those that have been designated by said attorneys for that purpose.

By leaving 2 true copies of same with a duly authorized person at their designated office.

~~By depositing true copies of same enclosed in a postpaid properly addressed wrapper, in the post office or official depository under the exclusive care and custody of the United Stated post office department within the State of New York.~~

Names of attorneys served, together with the names of the clients represented and the attorneys' designated addresses.

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Jeff Elyshevitz

Sworn to before me this
18 day of February, 1977

Michael DeSantis

MICHAEL DeSANTIS
Notary Public, State of New York
No. 03-0930908
Qualified in Bronx County
Commission Expires March 30, 1978